4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1358]

Jhanna Novikov: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Jhanna Novikov for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Ms. Novikov was convicted of one felony count under Federal law for smuggling goods into the United States. The factual basis supporting Ms. Novikov's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Ms. Novikov was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of April 8, 2022 (30 days after receipt of the notice), Ms. Novikov had not responded. Ms. Novikov's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory

Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if the FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On December 9, 2021, Ms. Novikov was convicted, as defined in section 306(l)(1) of FD&C Act, in the U. S. District Court for the Southern District of Florida-West Palm Beach Division, when the court accepted her guilty plea and entered judgment against her for the offense of smuggling goods into the United States, in violation of 18 U.S.C. 545. FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the indictment, filed on July 28, 2021, and the plea agreement, filed on September 30, 2021, both from Ms. Novikov's case, on July 25, 2018, Ms. Novikov agreed to treat the facial wrinkles of an individual who was an undercover investigator with the Florida Department of Health with "fillers" for $600 and "BOTOX" for $300. BOTOX, or botulinum neurotoxin Type A, is the most well-known neurotoxin approved by FDA to treat facial wrinkles. On August 10, 2018, the investigator returned to Ms. Novikov's residence for her "BOTOX" treatment, and as Ms. Novikov made preparations and drew a liquid into a syringe, agents from FDA's Office of Criminal Investigations (OCI) entered and took control of her residence. After obtaining a warrant, OCI agents searched Ms. Novikov's home. Agents seized various vials of white powder from Ms. Novikov's residence, including two labeled "NEUROXIN Botulinum Toxin Type A," 14 labeled "CASPIS," and one with no label. Analysis by the FDA Forensic Chemistry Center determined that the two Neuroxin vials, a

sample of four of the Caspis vials, and the unlabeled vial all contained botulinum toxin, the active ingredient in BOTOX; however, a search of FDA records revealed that these drugs had not been approved by FDA and were unapproved new drugs as well as misbranded drugs. Agents did not find any BOTOX or other FDA-approved drugs containing botulinum toxin in Ms. Novikov's home. A subsequent forensic examination of Ms. Novikov's cell phone, which had been seized by OCI agents, revealed that she had imported these unapproved new drugs from Mexico, in violation of the FD&C Act, and Ms. Novikov had been importing such drugs since 2016.

As a result of this conviction, FDA sent Ms. Novikov, by certified mail, on March 1, 2022, a notice proposing to debar her for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Ms. Novikov's felony conviction under Federal law for smuggling goods into the United States, in violation of 18 U.S.C. 545, was for conduct relating to the importation into the United States of any drug or controlled substance because she illegally imported unapproved new drugs containing botulinum toxin to use in treatments she conducted on individuals for money. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Ms. Novikov's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Ms. Novikov of the proposed debarment, offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Novikov received the proposal and notice of opportunity for a hearing at her residence on March 9, 2022. Ms. Novikov failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings And Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Jhanna Novikov has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Ms. Novikov is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Ms. Novikov is a prohibited act.

Any application by Ms. Novikov for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2021-N-1358 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at https://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: June 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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